SUPPORT FOR THE AMENDMENTS

Claims 11, 13, 27, and 33-58 were previously canceled.

Claim 12 is canceled herein.

Claims 1 and 10 have been amended.

The amendment to Claims 1 and 10 is supported by original Claims 1, 6, 10, and 12. Additional support for the amendment to Claim 1 is provided by the specification as originally filed, for example, at Examples 5, 6, and 8.

No new matter has been added by the present amendments.

REMARKS

Claims 1-10, 14-26, and 28-32 are pending in the present application.

The rejection of Claim 10 under 35 U.S.C. §112, second paragraph, is respectfully traversed.

The Examiner rejections Claim 10 as being indefinite alleging that the phrase "wherein at least one of said one or more additional amino acids is selected from the group consisting of arginine, glutamic acid, and aspartic acid" lacks antecedent basis. This allegation is incorrect as Claim 10 depends from Claim 6, which recites "The method of Claim 1, wherein said pharmaceutical composition further comprises *one or more additional amino acids*."

Accordingly, this ground of rejection should be withdrawn. Acknowledgement to this effect is requested.

The rejection of Claims 1-10, 12, 14-23, and 30-32 under 35 U.S.C. §102(b) over Krnjevic in view of Takagi et al, is respectfully traversed

Applicants note that Krnjevic in view of Takagi et al, do not disclose or suggest co-administration of a salt of lysine with glutamic acid or aspartic acid. Therefore, Krnjevic fails to disclose all the limitations of the claimed invention and, as such, cannot anticipate the claimed invention. Additionally, Takagi et al fail to disclose stress induced ulcers and cannot anticipate the claimed invention. To the extent that the Examiner intended this rejection to be an obviousness rejection, this is addressed below.

Withdrawal of this ground of rejection is requested.

The rejection of: (a) Claims 1-4, 6-10, 12, 14-23, and 30-32 under 35 U.S.C. §103(a) over Takagi et al, (b) Claims 1-4, 6-10, 12, 15-23, and 30-32 under 35 U.S.C. §103(a) over Niebes et al in view of Takagi et al, and (c) Claims 1-10, 12, 14-23, and 30-32 under 35 U.S.C. §103(a) over Krnjevic in view of Takagi et al, are respectfully traversed.

Takagi et al disclose compositions to treat gastric lesions induced by anti-inflammatory agents comprising at least one amino acid. The amino acids include L-lysine, L-arginine, L-glutamic acid and the like. However, there is no disclosure or suggestion that the lysine is in salt form with glutamic acid and/or that the composition also contains arginine as specifically defined in previously pending Claim 12, which is now added to Claim 1 of the present application.

Further, as the Examiner recognizes, Takagi et al fail to disclose or suggest that the gastric lesions disclosed therein have anything to do with stress. Indeed, in Takagi et al the sole stated objective is "the prevention of gastric lesions brought about by the administration of non-steroidal anti-inflammatory agents" (see, for example, column 1, lines 8-10, column 1, lines 48-52, etc.).

Specific reference is made to column 1, lines 65-67 where Takagi et al specifically disclose that the amino acid is to be administered "at every administration of the anti-inflammatory agent", which is to avoid any occurrence of gastric ulcers.

In contrast, the presently claimed invention is drawn to a "method of ameliorating, progress blocking, or therapeutically treating one or more stress-induced diseases" including gastric ulcers. Each of ameliorating, progress blocking, or therapeutically treating require that the subject to be treated actually have been diagnosed with or have a recognized need to treat the recited disorder or to bring about the recited effect (*Jansen v. Rexall Sundown Inc.*,

342 F.3d 1329, 1332, 68 USPQ2d 1154, 1158 (Fed. Cir. 2003)). In Takagi, on the other hand, the purpose of the administration is to prevent, which as the Office frequently states in enablement rejections, or to ensure that the disease state does not ever occur. Thus, preventing and "ameliorating, progress blocking, or therapeutically treating" are incompatible.

Certainly, there is nothing in Takagi et al to suggest that a salt of lysine, much less a salt of lysine together with either glutamic acid or aspartic acid, would have a reasonable expectation of success. The fact that that something has a preventative effect has absolutely no predictive value as to its ability to treat the thing that it should to prevent. For example, a bullet-proof vest may be excellent to prevent a bullet wound, but a doctor would never treat a gun-shot victim with a bullet-proof vest.

Moreover, there is no disclosure or suggestion in Takagi et al that lysine is used in combination with glutamic acid, as the Examiner recognized. In Takagi et al it is disclosed compositions comprising at least one amino acid, which the amino acids include L-lysine, L-arginine, L-glutamic acid and the like. But, it must be noted that Takagi et al do not provide any specific disclosure of lysine as specific amino acid is in salt form with other amino acid and which contains still other amino acid as defined in previously pending Claim 12, which is now added to Claim 1 of the present application.. Furthermore, there is no motivation toward the specific lysine in the salt form with glutamic acid and which contains arginine.

Niebes et al disclose a composition for treating stress induced ulcers (including gastric ulcers) comprising L-lysine (also may including L-arginine and L-ornithine). Krnjevic discloses compositions for treating conditions such as gastric ulcers with compositions comprising lysine orotate. However, neither Niebes et al nor Krnjevic disclose or suggest lysine in salt form with glutamic acid and that the composition further contains arginine.

Further reference is made to Example 5 (Fig. 6), Example 6 (Fig. 7), and Example 8 (Fig. 8). In these Examples, lysine in salt form with glutamic acid and the composition contains arginine. In each of these Examples, the composition of the claimed invention showed significant benefits are achieved from the present invention. In particular note is made of the aqueous mixture of lysine glutamate salt and arginine showed significant reduction of the areas of gastric bleeding in Example 5 and significantly prolonged time duration for searching action in Example 6. Example 8 contains the following additional disclosure "additionally, it is understood that the combined use of other specific amino acids, for example glutamic acid and arginine can further enhance the effect (of lysine)". Applicants submit that such an effect is not found in any of Takagi et al, Niebes et al or Krnjevic. Accordingly, Applicants submit that the claimed invention is not obvious in view these references individually or in any combination thereof.

Withdrawal of these grounds of rejection is requested.

Applicants submit that the present application is now in condition for allowance. Early notification of such action is earnestly solicited.

Respectfully submitted,

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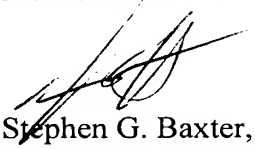

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